17112/RJC/as1/rn Attorney ID# 6296073

IN THE UNITED STATES DISTRICT CIRCUIT FOR THE NORTHERN DISTRICT OF ILLINOIS EASTERN DIVISION

MONIKA SWIECZKOWSKI, Individually as Mother & Next Best Friend of LEO SWIECZKOWSKI, and ARTUR SWIECZKOWSKI Plaintiff, v. BILLIONTOONE, INC., a Corporation, Defendant.	)	Case No.: 1:24-cv-11016

COMPLAINT AT LAW

NOW COME the Plaintiffs, MONIKA SWIECZKOWSKI, Individually as Mother & Next Best Friend of LEO SWIECZKOWSKI, and ARTUR SWIECZKOWSKI, by their attorneys, ANESI OZMON, LTD., and complaining of the Defendant, BILLIONTOONE, INC., and allege as follows:

I. INTRODUCTION

1. This action is brought pursuant to the laws of the State of Illinois to redress personal injury and economic loss sustained by what is termed under Illinois law as "wrongful birth" for extraordinary expenses and emotional distress.

II. JURISDICTION

2. Jurisdiction is based on Title 20 U.S.C. §1332. The parties are citizens of different states and the amount in controversy is in excess of $75,000.
3. At all times Plaintiffs MONIKA SWIECZKOWSKI AND ARTUR SWIECZKOWSKI resided in the Village of Hoffman Estates, County of Cook, State of Illinois.

4. Defendant BILLIONTOONE, INC., is a corporation headquartered in the City of Menlo Park, County of San Mateo, State of California.

5. Defendant engages in continuous trade and commerce in Illinois, by marketing and selling prenatal test kits claimed to detect Edwards syndrome and other genetic abnormalities to customers and ultimate consumers such as the SWIECZKOWSKIs through physician offices in Illinois.

6. The SWIECZKOWSKIs purchased a product of BILLIONTOONE, INC., in Illinois.

III. BACKGROUND

7. During pregnancy, noninvasive prenatal testing ("NIPT") has become popular in recent years to screen for chromosomal abnormalities and provide expectant mothers with an assessment of their risk for carrying a fetus with a chromosomal condition. Chromosomal conditions, also called aneuploidies, occur when a baby has an extra or missing chromosome, which can result in serious health complications and a severely shortened lifespan for the baby.

8. NIPT aims to detect genetic conditions early in pregnancy by testing cell-free DNA (cfDNA) from the placenta. Analyzing cfDNA from the placenta helps detect various chromosomal conditions without harming the fetus.[1]

9. Critically, NIPT is a screening test, which means that it is used to *estimate* whether a fetus has a higher or lower risk of having a certain chromosomal condition. By contrast, diagnostic tests, such as amniocentesis or chorionic villus sampling, provides a

[1]https://medlineplus.gov/genetics/understanding/testing/nipt/#:~:text=Analyzing%20cfDNA%20from%20the%20placenta,(aneuploidy)%20of%20a%20chromosome

definitive answer about whether a fetus has a certain condition. [2] However, both diagnostic procedures materially increase the risk for miscarriage.[3]

10. Expectant mothers and their doctors rely on the results of NIPT to decide whether to proceed with riskier invasive diagnostic testing. Ultimately then, NIPT helps expectant mothers make potentially life altering decisions - including whether to continue with the pregnancy. A pregnant patient whose child has one of these chromosomal disorders faces serious questions about the viability of the pregnancy and the prognosis and quality of life for any surviving newborn.

11. NIPT has not yet been authorized, cleared, or approved by the Food and Drug Administration (FDA). In fact, on April 16, 2022, the FDA issued a safety communication[4] warning patients and health care providers about the risks of false results with NIPT. The FDA encouraged "test developers to provide accurate, clear, and complete information about the performance of their tests, how they should be used, and what results may or may not mean."

IV. FACTS COMMON TO ALL COUNTS

Defendant's Marketing of its Noninvasive Prenatal Test

12. Defendant, BILLIONTOONE, INC., markets and sells "UNITY Complete," an NIPT that, according to Defendant, sets "[t]he New Standard In Prenatal Care." UNITY Complete includes the "UNITY Fetal Risk Screen," which screens for recessive

[2] https://www.acog.org/womens-health/infographics/cell-free-dna-prenatal-screening-test
[3]https://www.cdc.gov/mmwr/preview/mmwrhtml/00038393.htm#:~:text=Both%20procedures%20increase%20the%20risk,resulting%20from%20CVS%20(2).
[4] https://www.fda.gov/medical-devices/safety-communications/genetic-non-invasive-prenatal-screening-tests-may-have-false-results-fda-safety-communication

conditions not relevant here, and the "UNITY Aneuploidy Screen," which screens for chromosomal conditions such as Trisomy 18, also known as Edwards syndrome.

13. Edwards syndrome is a condition wherein a baby is born with three copies of chromosome 18 instead of two, resulting in serious birth defects. Edwards syndrome has no treatment and is usually fatal within the first year of life.

14. On and prior to February 1, 2023, BILLIONTOONE, INC., through its various marketing channels, including its website and other marketing materials, represented to physicians, including Alex B. Lipowich, M.D., a board-certified obstetrician physician who treated the SWIECZKOWSKIs, and to expectant parents generally, including the SWIECZKOWSKIs, the following claims about its UNITY Complete test:

    a. "UNITY Fetal Risk Screen leverages cell-free DNA to provide **direct insights to the fetus**, translating to ~3x increase in detection of affected pregnancies compared to traditional carrier screening." (emphasis added). **See Exhibit A**

    b. "The first and only test that uses cell-free DNA to provide precise **fetal insights** for both recessive and chromosomal conditions." (emphasis added). **See Exhibit B**

    c. "**Know** More. **Know** Early." (emphasis added). **See Exhibit B**

    d. "UNITY Complete provides early **detection** of severe genetic conditions early in a pregnancy. **Knowing early** allows access to timely interventions and treatments." (emphasis added). **See Exhibit B**

    e. "A single blood draw, as early as 10 weeks is all it takes to **Know** More and **Know** Early." (emphasis added). **See Exhibit C**

15. While UNITY Complete can provide patients with an estimated risk of a baby having a certain chromosomal or genetic condition, UNITY Complete cannot definitively diagnose such conditions - the potential for false positives and false negatives remain. Therefore, contrary to Defendant's claims, a patient cannot "know" that their baby will have a chromosomal condition from a single blood draw.

16. Importantly, because cell-free DNA derives from the placenta, UNITY Complete is not providing "precise **fetal** insights" or "direct insight **into the fetus**" but rather, only the placenta. To this point, cell free 'fetal' DNA in maternal blood originates from the cytotrophoblast and is not always concordant with true fetal DNA.

17. Regarding the performance of the UNITY Complete Aneuploidy Screen, Defendant's provider brochure, as shown on its website prior to February 1, 2023, advertised the following metrics for Trisomy 18: **See Exhibit D**

Sensitivity[5]	99.9% (99.0%-100%)
Specificity[6]	>99.9%

18. However, numerous medical studies list the sensitivity to detect Trisomy 18 as ranging from 96.15%[7] to 98.83%[8], as opposed to 99.9%, as Defendant represents.

[5] Sensitivity, or true positive rate, quantifies a test's ability to return a positive result if the patient has the disease in question. It is the probability that a test result will be positive when the disease is present. "A highly sensitive test means that there are few false negative results." https://www.health.ny.gov/diseases/chronic/discreen.htm#:~:text=Sensitivity%20refers%20to%20a%20test's,have%20a%20disease%20as%20negative.

[6] Specificity, or true negative rate, quantifies a tests ability to correctly identify those who do not have the disease in question. Specificity is the probability that a test result will be negative when the disease is not present.

[7] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9522523/
[8] https://obgyn.onlinelibrary.wiley.com/doi/10.1002/pd.6357

Plaintiff's Physician, Alex B. Lipowich, M.D., Recommends Defendant's UNITY Complete test

19. Plaintiffs MONIKA SWIECZKOWSKI AND ARTUR SWIECZKOWSKI became pregnant with LEO sometime toward the end of 2022. The pregnancy was consummated through in-vitro fertilization.

20. MONIKA SWIECZKOWSKI was 35 years old at the time of the pregnancy. MONIKA's advanced maternal age, in conjunction with her in-vitro fertilization, placed the SWIECZKOWSKIs and LEO at increased risk for various maternal and fetal complications.

21. On January 17, 2023, the SWIECZKOWSKIs established prenatal care with the office of Alex B. Lipowich, M.D., a board-certified obstetrician.

22. On and prior to February 1, 2023, Defendant marketed its UNITY Complete test to Alex B. Lipowich, M.D., directly through various marketing channels, including representations contained on Defendant's website.

23. In Defendant's marketing of its UNITY Complete test to Alex B. Lipowich, M.D., directly, as well as other physicians and expectant parents generally, Defendant made the deceptive and/or misleading claims listed in paragraphs 14-18 *supra*.

24. Defendant made the aforementioned deceptive and/or misleading claims to physicians, including Alex B. Lipowich, M.D., intending that it reach the SWIECZKOWSKIs and other similarly situated Plaintiffs.

25. On February 1, 2023, Alex B. Lipowich, M.D., recommended that the SWIECZKOWSKIs undergo UNITY Complete to screen their baby for chromosomal conditions, including Edwards syndrome.

26. As a result of Defendant's deceptive and/or misleading claims listed in paragraphs 14 -

18 *supra*, Alex B. Lipowich, M.D., offered and recommended that the SWIECZKOWSKIs use Defendant's UNITY Complete test specifically.

27. On February 1, 2023, the SWIECZKOWSKIs consented to using UNITY Complete and a blood sample was collected from MONIKA at the office of Alex B. Lipowich, M.D., and then sent to Defendant's laboratory in California for processing and analysis.

28. The Office of Alex B. Lipowich, M.D., agreed to accept payment for the UNITY Complete test through the SWIECZKOWSKIs' insurer instead of requesting the SWIECZKOWSKIs to pay for the UNITY Complete test first and then later request reimbursement from the insurance company.

29. The SWIECZKOWSKIs became consumers of the UNITY Complete test when they consented to the test and paid for the same, through their insurance coverage, at the recommendation of their obstetrician, Alex B. Lipowich, M.D..

Defendant's UNITY Complete Results Misrepresent that there was a less than 1 in 10,000 chance of LEO having Trisomy 18

30. On February 3, 2023, the Defendant received the blood sample from Alex B. Lipowich, M.D., 's office.

31. On February 9, 2023, Defendant transmitted the SWIECZKOWSKIs' UNITY Complete results to the SWIECZKOWSKIs via the office of Alex B. Lipowich, M.D. See **Exhibit E**.

32. As reflected on the attached Exhibit E, Defendant summarized the results of the SWIECZKOWSKIs' test for Edward Syndrome as follows:

CONDITIONS SCREENED	FETAL RISK *by* NIPT	RISK *Before* NIPT	RISK *After* NIPT
Trisomy 18	Low Risk	1 in 411	< 1 in 10,000

33. MONIKA received and reviewed the results of the UNITY Complete test in the office

with Alex B. Lipowich, M.D., on or around February 14, 2023.

34. Specifically, MONIKA understood, per the UNITY Complete test results which were shown to her and made a part of her medical record, that her baby had a less than 1 in 10,000 chance, or 0.0001 of having Trisomy 18, or Edwards syndrome. **See Exhibit E**.

35. MONIKA further understood, per the UNITY Complete test results which were shown to her and made a part of her medical record, that before taking the UNITY Complete test, the risk of LEO having Edwards syndrome was 1 in 411. **See Exhibit E.**

36. Throughout the remainder of her pregnancy, MONIKA relied on Defendant's representation that the probability of LEO having Edwards syndrome was less than 1 in 10,000.

37. The representation by Defendant to MONIKA that her baby had a less than 1 in 10,000 chance of having Trisomy 18 is false and/or misleading because said calculation fails to account for the chance of a false negative.

38. Per various medical studies and scientific research, false negative rates for Edwards syndrome have been shown to be as high as 7.9%.

39. Defendant's own study[9] revealed a false negative rate of ~2.4% for Edwards syndrome.

40. Despite the known prevalence of NIPT producing false negatives for Edwards syndrome, Defendant falsely represented to the SWIECZKOWSKIs, and/or mislead them into believing, that the probability of LEO having Edwards syndrome was less than 1 in 10,000 when the actual chance was significantly higher.

41. Defendant's marketing, as described in paragraphs 14-18 *supra*, as well as its test results communicated directly to the SWIECZKOWSKIs, were false and deceptive as Defendant

[9] https://www.remedypublications.com/open-access/performance-characteristics-of-a-next-generation-sequencing-based-cfdna-assay-for-10032.pdf

knew or should have known that the information contained therein would provide the impression to physicians, including Alex B. Lipowich, M.D., who specifically recommended UNITY Complete to MONIKA, as well as patients, including MONIKA, that a "low risk" result meant that the patient had a less than 1 in 10,000 chance of having Trisomy 18. .

42. Alex B. Lipowich, M.D., as an obstetrician who provides care to expectant mothers, and the SWIECZKOWSKIs, as a pregnant couple near or over 35 and concerned about genetic defects more prevalent to older mothers, were the very consumers Defendant targeted by its advertising and marketing.

43. The SWIECZKOWSKIs were led to believe, through the false and misleading representations made by Defendant, and did believe, that LEO's chances of having Trisomy 18 were less than 1 in 10,000.

Defendant's Deception leads to Wrongful Birth

44. On March 30, 2023, Nicole Masse, M.D., reviewed a fetal ultrasound which showed that LEO had a clubbed foot.

45. A finding of clubbed feet is idiopathic roughly 80% of the time, and the remainder is associated with genetic abnormalities.

46. Dr. Masse discussed invasive testing to further investigate the etiology of LEO's clubbed foot but MONIKA declined because Defendant had already represented to her that the chances of LEO having a chromosomal abnormality were less than 1 in 10,000..

47. On April 6, 2023, MONIKA attended a genetic counseling session with certified genetic counselor Shannon Hefferan, MS, CGC.

48. Ms. Hefferan discussed the risks and benefits of invasive testing, and MONIKA

declined, as she was uncomfortable with the associated risks of the procedure, which included miscarriage.

49. Monika further reasoned that LEO essentially had zero chance of having Edwards syndrome, per the false and misleading representations by Defendant, and if her baby had special needs or some other less concerning birth defect, it would not have changed her pregnancy management decision.

50. On May 22, 2023, another fetal ultrasound was done. The test was interpreted by Christine Kovac, MD, a maternal-fetal medicine specialist.

51. The test revealed a mixture of abnormal and reassuring findings. Specifically, the ultrasound showed the possibility of fetal growth restriction, along with the known clubbed foot, however the fluid was normal, the umbilical artery Dopplers were normal, and a Biophysical Profile score was a perfect 8 out of 8.

52. Dr. Kovac broached invasive testing to diagnose or rule out a possible chromosomal etiology, but MONIKA again declined because she continued to rely on the false and deceptive representations made by Defendant that LEO essentially had zero chance of having Edwards syndrome and therefore the risks outweighed the benefits of diagnostic testing.

53. Dr. Kovac recommended MONIKA submit to a fetal MRI and MONIKA acquiesced. The test was inconclusive with a differential diagnosis that included magna cisterna mangna versus Blake's pouch cyst, both of which are typically benign conditions.

54. For the remainder of her pregnancy, MONIKA attended numerous physician visits and underwent serial fetal testing, including fetal ultrasounds, biophysical profiles, fetal echocardiograms, laboratory testing, and physical exams. Throughout, MONIKA relied

on the representations made by Defendant that LEO had essentially zero chance of having Edwards syndrome.

55. On August 7, 2023, MONIKA delivered baby LEO SWIECZKOWSKI via caesarean section. The procedure was performed by Alex B. Lipowich, M.D. LEO was transferred to the neonatal intensive care unit (NICU) immediately following his birth.

56. A blood test subsequently performed in the NICU revealed that LEO did, in fact, have Trisomy 18, or Edwards syndrome, despite the representations by Defendant that such an outcome was essentially not possible.

57. LEO SWIECZKOWSKI survived for approximately three weeks in the neonatal intensive care unit before finally passing away secondary to Edwards syndrome.

58. At MONIKA's postpartum appointment with Alex B. Lipowich, M.D., on September 18, 2023, Dr. Lipowich wrote in his progress note "we won't be using Unity anymore."

59. If not for Defendant's conduct in failing to properly disclose the true prevalence of false negatives for Trisomy 18 to MONIKA through her test results, and Defendant's conduct of providing deceptive and/or misleading information to Alex B. Lipowich, M.D., through its marketing materials and website, the SWIECZKOWSKIs would have consented to diagnostic testing which would have revealed that LEO did, in fact, have Edwards syndrome and the SWIECZKOWSKIs would have timely terminated the pregnancy.

60. The birth and death of LEO SWIECZKOWSKI caused the SWIECZKOWSKIs to have, and they continue to have, extraordinary pain, suffering, and emotional distress, in addition to medical bills.

V. CAUSES OF ACTION

COUNT I
Violation of the Illinois Consumer Fraud and Deceptive Business Practices Act (815 Ill. Comp. Stat. § 505/1, et seq.)

61. Plaintiffs, The SWIECZKOWSKIs, bring this cause of action pursuant to 815 ILCS 505/2, the Consumer Fraud and Deceptive Business Practices Act, in their individual capacities.

62. Section 1(e) defines a consumer:

> (e) The term "consumer" means any person who purchases or contracts for the purchase of merchandise not for resale in the ordinary course of his trade or business but for his use or that of a member of his household.

63. Defendant, BILLIONTOONE, INC., sold the UNITY Complete test to Illinois consumers and patients of obstetrician-gynecologists through physicians such as Alex B. Lipowich, M.D.

64. The SWIECZKOWSKIs were consumers of the UNITY Complete test as they purchased the test through the medical office of Alex B. Lipowich, M.D., from Defendant.

65. Section 2 of the Consumer Fraud and Deceptive Business Practices Act provides:

> Sec. 2. Unfair methods of competition and unfair or deceptive acts or practices, including but not limited to the use or employment of any deception fraud, false pretense, false promise, misrepresentation or the concealment, suppression or omission of any material fact, with intent that others rely upon the concealment, suppression or omission of such material fact, or the use or employment of any practice described in Section 2 of the "Uniform Deceptive Trade Practices Act", approved August 5, 1965, in the conduct of any trade or commerce are hereby declared unlawful whether any person has in fact been misled, deceived or damaged thereby. In construing this section consideration shall be given to the interpretations of the Federal Trade Commission and the federal courts relating to Section 5 (a) of the Federal Trade Commission Act.

66. Defendant made deceptive statements on its website, in the informational brochures and

other materials provided to physicians, including Alex B. Lipowich, M.D., who treated MONIKA, and in the test results Defendant provided to the SWIECZKOWSKIs

67. Defendant used unfair and/or deceptive acts or practices in one or more of the following ways:

    a. Misrepresenting that UNITY Complete allows a patient to "know" that their baby will have a chromosomal condition from a single blood draw;
    b. Misrepresenting that the UNITY Complete had an over 99.9% sensitivity rate in detecting Trisomy 18 abnormalities;
    c. Misrepresenting the limitations of the UNITY Complete test;
    d. Failing to properly disclose the limitations of the UNITY Complete test;
    e. Misrepresenting the probability and rate at which the UNITY Screen could produce false negative results;
    f. Failing to properly disclose the rate at which UNITY Screen could produce false negative results;
    g. Misrepresenting that UNITY Complete could provide "precise **fetal** insights" and "direct insights into the **fetus**" when only **placental** DNA was being tested (emphasis added);
    h. Using deceptive statements to create the image, impression and belief by consumers, including the SWIECZKOWSKIs, and physicians, including Alex B. Lipowich, M.D., that MONIKA's chances of having a baby with Trisomy 18 was less than 1 in 10,000;
    i. Misrepresenting that the risk of Trisomy 18 for MONIKA's fetus was less than 1 in 10,000.

68. Defendant made the foregoing misrepresentations with the intent that Physicians, including Alex B. Lipowich MD., and expectant parents, including the SWIECZKOWSKIs, would rely on such misrepresentations.

69. Defendant knew or had reason to know that the foregoing misrepresentations were false, unfair or deceptive to the SWIECZKOWSKIs and others similarly situated to Plaintiffs.

70. Defendant made the foregoing misrepresentations or engaged in the foregoing deceptive

acts and/or practices in the course of commerce.

71. Due to Defendant's misrepresentations and the inherently unfair practice of committing misrepresentations against the public by intentionally misrepresenting and/or concealing material information, Defendant's acts constitute unfair or deceptive acts and practices.
72. Defendant's actions are prohibited by the Consumer Fraud and Deceptive Business Practices Act.
73. As a direct result of Defendant's deceptive statements, the SWIECZKOWSKIs were led to believe that there was essentially zero chance that their baby would be born with Trisomy 18, when the risk was actually far greater.
74. The SWIECZKOWSKIs reasonably and justifiably relied on these false and misleading statements, which created a false sense of security for the SWIECZKOWSKIs, causing them to forgo diagnostic testing which would have revealed that LEO, in fact, had Trisomy 18.
75. But for the false and misleading statements of Defendant, the SWIECZKOWSKIs would have learned that LEO had Trisomy 18, which is usually fatal before birth or within the first year of life, and the SWIECZKOWSKIs would have terminated the pregnancy.
76. Because of the false and misleading statements of Defendant, the SWIECZKOWSKIs instead suffered a "wrongful birth," leading them to experience pain, suffering, emotional distress, and financial loss.

WHEREFORE, the Plaintiffs, MONIKA SWIECZKOWSKI, Individually as Mother & Next Best Friend of LEO SWIECZKOWSKI, and ARTUR SWIECZKOWSKI, pray for entry of judgment against Defendant, BILLIONTOONE, INC., for the damages incurred by Plaintiffs in excess of $50,000, plus punitive damages, together with the costs of this action.

COUNT II
Common Law Fraud

77. Plaintiffs incorporate and reallege the foregoing allegations of fact.

78. Defendant, BILLIONTOONE, INC., made false statements of material fact in one or more of the following ways:

    a. Misrepresenting that UNITY Complete allows a patient to "know" that their baby will have a chromosomal condition from a single blood draw;
    b. Misrepresenting that the UNITY Complete had an over 99.9% sensitivity rate in detecting Trisomy 18 abnormalities;
    c. Misrepresenting the limitations of the UNITY Complete test;
    d. Failing to properly disclose the limitations of the UNITY Complete test;
    e. Misrepresenting the probability and rate at which the UNITY Screen could produce false negative results;
    f. Failing to properly disclose the rate at which UNITY Screen could produce false negative results;
    g. Misrepresenting that UNITY Complete could provide "precise **fetal** insights" and "direct insights into the **fetus**" when only **placental** DNA was being tested (emphasis added);
    h. Using deceptive statements to create the image, impression and belief by consumers, including the SWIECZKOWSKIs, and physicians, including Alex B. Lipowich, M.D., that MONIKA's chances of having a baby with Trisomy 18 was less than 1 in 10,000;
    i. Misrepresenting that the risk of Trisomy 18 for MONIKA's fetus was less than 1 in 10,000.

79. Defendant knew or had reason to know that the foregoing misrepresentations were false, to the SWIECZKOWSKIs and others similarly situated to Plaintiffs.

80. Defendant intended to induce physicians, including Alex B. Lipowich, M.D., to rely on the foregoing statements in deciding to use and recommend UNITY Complete to patients, including the SWIECZKOWSKIs.

81. Alex B. Lipowich, M.D., reasonably and justifiably relied on the truth of the Defendant's foregoing statements in recommending Defendant's UNITY Complete test.

82. Defendant also intended to induce the SWIECZKOWSKIs to rely on the foregoing statements in using UNITY Complete and understanding their test results.

83. Defendant knew or should have known that the SWIECZKOWSKIs would rely on the foregoing statements, as Defendant was aware that the test results would be used by expectant parents like the SWIECZKOWSKIs to make critical decisions about their pregnancies.

84. As a direct result of Defendant's false and misleading statements, the SWIECZKOWSKIs were led to believe that there was essentially zero chance that their baby would be born with Trisomy 18, when the risk was actually far greater.

85. The SWIECZKOWSKIs reasonably and justifiably relied on these false and misleading statements, which created a false sense of security for the SWIECZKOWSKIs, causing them to forgo diagnostic testing which would have revealed that LEO, in fact, had Trisomy 18.

86. But for the false and misleading statements of Defendant, the SWIECZKOWSKIs would have learned that LEO had Trisomy 18, which is usually fatal before birth or within the first year of life, and the SWIECZKOWSKIs would have timely terminated the pregnancy.

87. Because of the false and misleading statements of Defendant, the SWIECZKOWSKIs suffered a "wrongful birth," leading them to experience continued pain, suffering, emotional distress, and financial loss.

WHEREFORE, the Plaintiffs, MONIKA SWIECZKOWSKI, Individually as Mother & Next Best Friend of LEO SWIECZKOWSKI, and ARTUR SWIECZKOWSKI, pray for entry of

judgment against Defendant BILLIONTOONE, INC., for the damages incurred by Plaintiffs in excess of $50,000, plus punitive damages, together with the costs of this action.

COUNT III
Negligent Misrepresentation

88. Plaintiffs incorporate and reallege the foregoing allegations of fact.

89. At all relevant times, Defendant had a duty to provide the SWIECZKOWSKIs with accurate and reliable information regarding the UNITY Complete test and the SWIECZKOWSKIs' test results. This duty arises from the business relationship between the parties and direct marketing of the test to MONIKA's personal physician, Alex B. Lipowich, M.D., who then recommended the test to the SWIECZKOWSKIs.

90. Defendant, BILLIONTOONE, INC., negligently made false statements of material fact in one or more of the following ways:

    a. Misrepresenting that UNITY Complete allows a patient to "know" that their baby will have a chromosomal condition from a single blood draw;
    b. Misrepresenting that the UNITY Complete had an over 99.9% sensitivity rate in detecting Trisomy 18 abnormalities;
    c. Misrepresenting the limitations of the UNITY Complete test;
    d. Failing to properly disclose the limitations of the UNITY Complete test;
    e. Misrepresenting the probability and rate at which the UNITY Screen could produce false negative results;
    f. Failing to properly disclose the rate at which UNITY Screen could produce false negative results;
    g. Misrepresenting that UNITY Complete could provide "precise **fetal** insights" and "direct insights into the **fetus**" when only **placental** DNA was being tested (emphasis added);
    h. Using deceptive statements to create the image, impression and belief by consumers, including the SWIECZKOWSKIs, and physicians, including Alex B.

Lipowich, M.D., that MONIKA's chances of having a baby with Trisomy 18 was less than 1 in 10,000;

i. Misrepresenting that the risk of Trisomy 18 for MONIKA's fetus was less than 1 in 10,000.

91. Defendant was careless and/or negligent in determining the truth of the aforementioned statements.

92. Defendant intended to induce physicians, including Alex B. Lipowich, M.D., to rely on the foregoing statements in deciding to use and recommend UNITY Complete to patients, including the SWIECZKOWSKIs.

93. Alex B. Lipowich, M.D., reasonably and justifiably relied on the truth of the Defendant's foregoing statements in recommending Defendant's UNITY Complete test.

94. Defendant also intended to induce the SWIECZKOWSKIs to rely on the foregoing statements in using UNITY Complete and understanding their test results.

95. Defendant knew or should have known that the SWIECZKOWSKIs would rely on the foregoing statements, as Defendant was aware that the test results would be used by expectant parents like the SWIECZKOWSKIs to make critical decisions about their pregnancies.

96. As a direct result of Defendant's negligent misrepresentation, the SWIECZKOWSKIs were led to believe that there was essentially zero chance that their baby would be born with Trisomy 18, when the risk was actually far greater.

97. The SWIECZKOWSKIs reasonably and justifiably relied on these false and misleading statements, which created a false sense of security for the SWIECZKOWSKIs, causing them to forgo diagnostic testing which would have revealed that LEO, in fact, had Trisomy 18.

98. But for the false and misleading statements of Defendant, the SWIECZKOWSKIs would have learned that LEO had Trisomy 18, which is usually fatal before birth or within the first year of life, and the SWIECZKOWSKIs would have terminated the pregnancy.

99. Because of the false and misleading statements of Defendant, the SWIECZKOWSKIs suffered a "wrongful birth," leading them to experience continued pain, suffering, emotional distress, and financial loss.

WHEREFORE, the Plaintiffs, MONIKA SWIECZKOWSKI, Individually as Mother & Next Best Friend of LEO SWIECZKOWSKI, and ARTUR SWIECZKOWSKI, pray for entry of judgment against Defendant BILLIONTOONE, INC., for the damages incurred by Plaintiffs in excess of $50,000, plus punitive damages, together with the costs of this action.

/s/Robert J. Cheris
Robert J. Cheris, Attorney for Plaintiffs

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EXHIBIT A

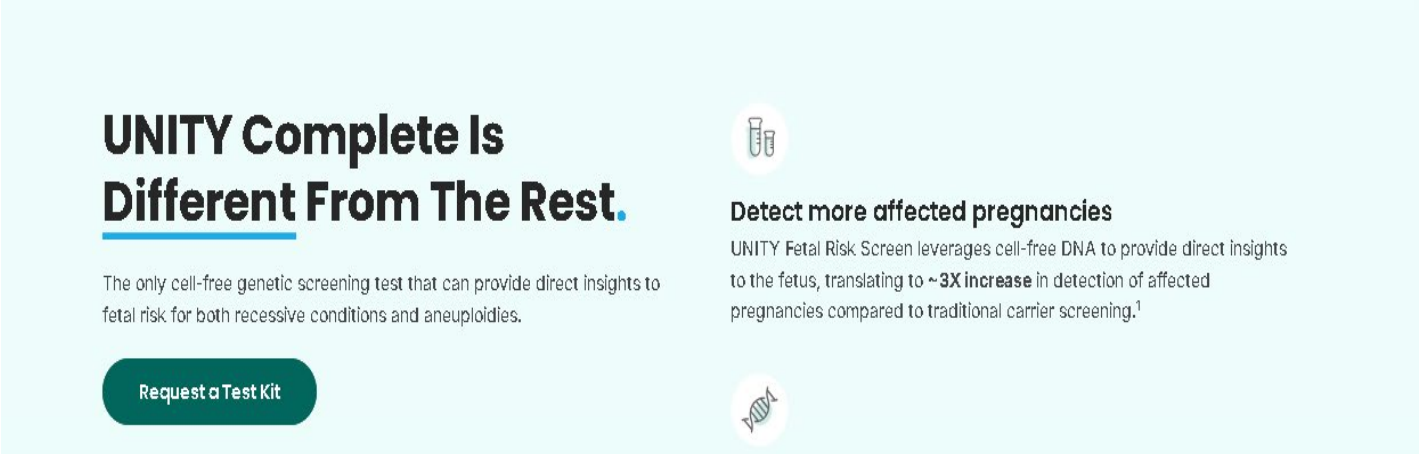

UNITY Complete Is Different From The Rest.
The only cell-free genetic screening test that can provide direct insights to fetal risk for both recessive conditions and aneuploidies.
Request a Test Kit
Detect more affected pregnancies
UNITY Fetal Risk Screen leverages cell-free DNA to provide direct insights to the fetus, translating to ~3X increase in detection of affected pregnancies compared to traditional carrier screening.[1]

EXHIBIT B

Discover What Sets UNITY Complete Apart.

UNITY Complete Fetal Risk Screen is prenatal screening reimagined. It has earned a spot in AJHG's Genomic Medicine Year in Review: 2023, recognized as a top 10 key advancement in applying genomics to clinical care.[1]

First-and-only tests

The first and only test that uses cell-free DNA to provide precise fetal insights for both recessive and chromosomal conditions.

UNITY Complete evaluates the baby's genetic information, which can be found in mom's bloodstream. By doing so, it can determine how likely it is that baby will be born with specific genetic conditions, even without information from the baby's father.

Reassurance for 99% of pregnancies

With UNITY Fetal Risk Screen, the vast majority of patients will learn that there is a very low chance their baby will be born with serious recessive conditions, such as Cystic Fibrosis, Spinal Muscular Atrophy, or other conditions.

This can provide peace of mind and reassurance to more than 99% of pregnancies tested with UNITY Fetal Risk Screen.[2]

Testing of father not needed

Unlike other genetic testing options, UNITY Complete does not rely on the father for an informative result. This is different from traditional carrier screening, which relies on information from the baby's father.

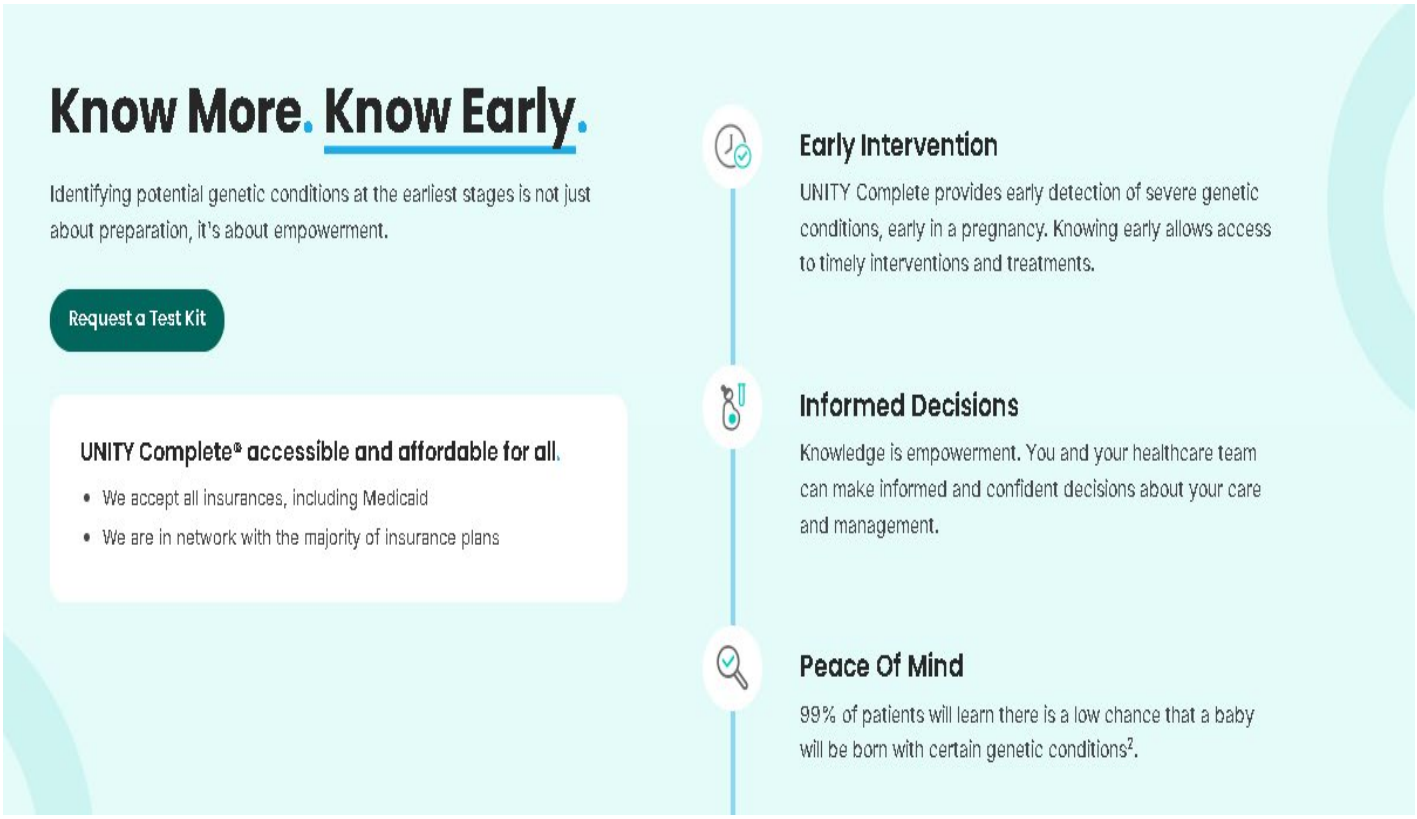

Know More. Know Early.
Identifying potential genetic conditions at the earliest stages is not just about preparation, it's about empowerment.
Request a Test Kit
UNITY Complete® accessible and affordable for all.
We accept all insurances, including Medicaid
We are in network with the majority of insurance plans
Early Intervention
UNITY Complete provides early detection of severe genetic conditions, early in a pregnancy. Knowing early allows access to timely interventions and treatments.
Informed Decisions
Knowledge is empowerment. You and your healthcare team can make informed and confident decisions about your care and management.
Peace Of Mind
99% of patients will learn there is a low chance that a baby will be born with certain genetic conditions[2].

EXHIBIT C

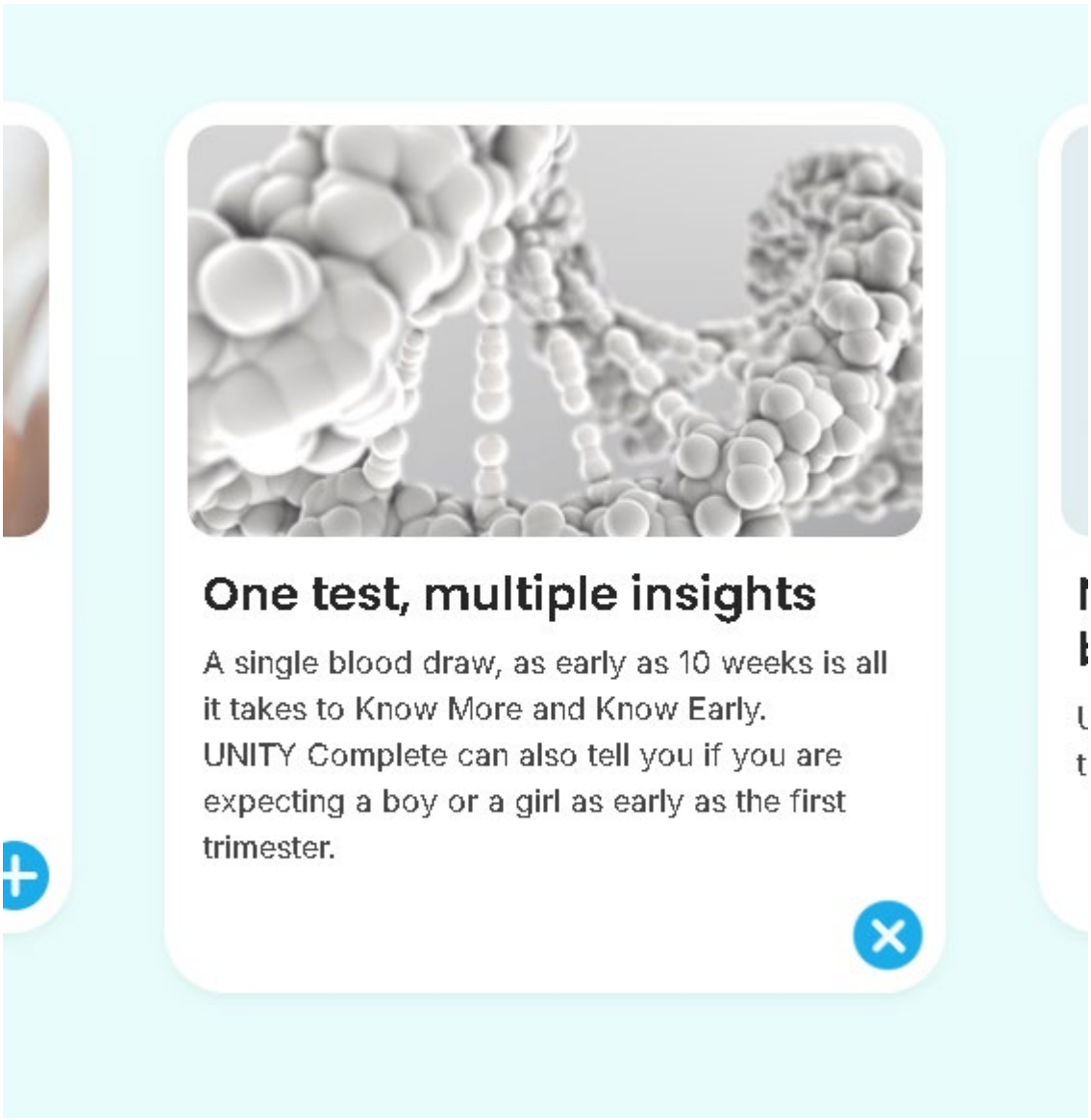
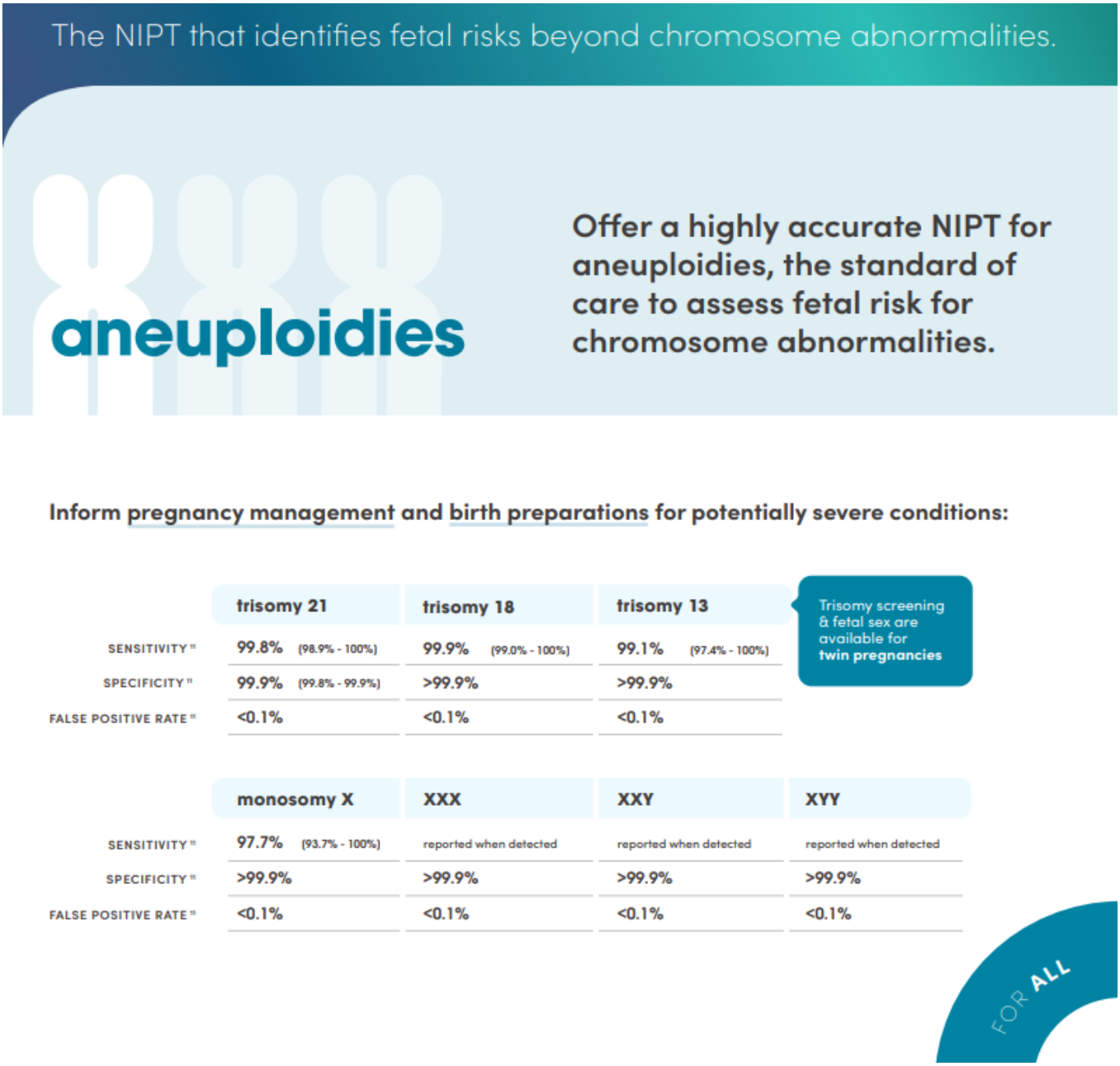

One test, multiple insights
A single blood draw, as early as 10 weeks is all it takes to Know More and Know Early.
UNITY Complete can also tell you if you are expecting a boy or a girl as early as the first trimester.

EXHIBIT D


The NIPT that identifies fetal risks beyond chromosome abnormalities.
aneuploidies
Offer a highly accurate NIPT for aneuploidies, the standard of care to assess fetal risk for chromosome abnormalities.
Inform pregnancy management and birth preparations for potentially severe conditions:
trisomy 21
trisomy 18
trisomy 13
Trisomy screening & fetal sex are available for twin pregnancies
SENSITIVITY
99.8% (98.9% - 100%)
99.9% (99.0% - 100%)
99.1% (97.4% - 100%)
SPECIFICITY
99.9% (99.8% - 99.9%)
>99.9%
>99.9%
FALSE POSITIVE RATE
<0.1%
<0.1%
<0.1%
monosomy X
XXX
XXY
XYY
SENSITIVITY
97.7% (93.7% - 100%)
reported when detected
reported when detected
reported when detected
SPECIFICITY
>99.9%
>99.9%
>99.9%
>99.9%
FALSE POSITIVE RATE
<0.1%
<0.1%
<0.1%
<0.1%
FOR ALL

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E support@unityscreen.com
BILLION TO ONE

PATIENT		SAMPLE		PROVIDER	
First Name	Monika	Sample Type	Blood	Provider	Alex Lipowich
Last Name	Swieczkowski	Date Collected	02/01/2023	Clinic Address	800 Biesterfield Road Brock Building Suite 2004 Elk Grove Village, IL 60007
DOB	[redacted]	Date Received	02/03/2023		
Ethnicity	Northern European/White	Accession ID	1377561G2980		
Gender	Female	Requisition ID	1377561G2980-1	Phone Number	8474379505
Gestational Age	11w0d	Date Reported	02/08/2023	Fax Number	8479815572
Medical Record #	N/A				

UNITY™ Complete: **Aneuploidy Screen**

Singleton Gestation

SUMMARY OF RESULTS

LOW RISK FETUS | **MALE** FETAL SEX | **3.9%** FETAL FRACTION

CONDITIONS SCREENED	FETAL RISK *by* NIPT	RISK *Before* NIPT	RISK *After* NIPT
Trisomy 21	Low Risk	1 in 140	<1 in 10,000
Trisomy 18	Low Risk	1 in 411	<1 in 10,000
Trisomy 13	Low Risk	1 in 1233	<1 in 10,000
Monosomy X	Low Risk	1 in 250	<1 in 10,000
Sex Chromosome Aneuploidy (XXX / XXY / XYY)	Not Detected		

RECOMMENDED FOLLOW-UP

Genetic counseling is available to review the implications of this result.

The patient may contact BillionToOne at (650) 460-2551 to schedule an appointment for a complimentary telephone genetic consultation to review these results. A genetic counselor can also be found at www.nsgc.org.

Doesn't want to know sex.

Interpretation *next page* ›

PULL CHART
FEB 10 2023
Rvd ___
Filed ___

BillionToOne Inc. CLIA ID: 05D2167800. CLF: 00353741. Lab Director: Joseph Michael Anderson, MD. Report version: aneuploidy_v20220909